

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claim Status

Claims 1-10, 12-43 and 58-79 are currently pending in the application. Claims 7, 8, 20, and 65 are withdrawn from consideration.

Claims 1, 3, 12, 17-19, 26, 32, 38, and 65 have been amended to address formal matters raised by the Examiner. Claim 1 has also been amended to better highlight distinctions over the cited prior art. Claim 11 has essentially been incorporated into claim 1, and claim 11 is canceled without prejudice hereby. Claims 12-16 and 60 have been amended to change dependency.

Claims 44-57 were previously cancelled without prejudice.

Claims 78 and 79 have been added. Claims 78 and 79 are of the same scope, and directed to the same subject matter as original claims 66 and 73.

No new matter has been introduced by any of the amendments or new claims.

Drawings

In sections 4 and 23 of the Office Action, the Examiner has repeated his objections to the drawings. In particular, the Examiner argues that the drawings do not depict an implant wherein *only one of two extensions includes a plurality of hinges*, as recited in claim 7. The examiner further argues that the drawings do not depict an implant with *extensions extending axially away or axially towards the body prior to moving apart of the anchor points*, as recited in claims 20 and 21.

Although applicant respectfully continues to disagree with the Examiner, to avoid further conflict on this issue, a new Fig. 8G is hereby added, and pages 11 and 15 of the specification are amended to describe the new figure.

With respect to the limitations in claims 20 and 21, applicant respectfully submits that it is very difficult to imagine a figure which better depicts a stent having extensions which may extend axially away the body prior to moving apart of the anchor points than Figs. 9A-9C. Likewise, it is very difficult to imagine a figure which better depicts a stent having extensions which may extend axially toward the body prior to moving apart of the anchor

points than Fig. 9E or 9F. Accordingly, to make clear that Figs. 9A-9C and 9e and 9F are intended to cover such embodiments, page 19 is hereby amended to state:

It should be noted that Figs. 9A-9C are also intended to depict exemplary embodiments of the invention in which a stent includes extensions which may extend axially away the body prior to moving apart of the anchor points. Likewise, Figs. 9E and 9F is also intended to depict exemplary embodiments having extensions which may extend axially toward the body prior to moving apart of the anchor points.

It is respectfully submitted that this overcomes the Examiner's objections to the drawings.

Claims Objections

In Section 5 of the Office Action, the Examiner objected to Claims 1, 3, 12, 17-19, and 32 because of various informalities. These claims have been amended according to the Examiner suggestions. No new matter has been added.

35 U.S.C. § 112 Rejections

In sections 6-12 of the Office Action, the Examiner has rejected Claims 1-6, 11-19, 21-30, 34-38, 58-60, 64, and 75-77 under 35 U.S.C 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter. Without prejudice and to better clarify the limitations in question, these claims have been amended to overcome the rejection.

In claim 1, "two implant points" has been amended to read *at least two implant points*. This amendment also overcomes the rejection of claims 2-6, 11-19, 21-30, 34-38, 58-60, 64, and 75-77 as being dependent on claim 1.

Further regarding these dependent claims, in claim 26, "said plurality of hinges" has been amended to read "said at least two hinges", claim 38 has been made dependent on claim 30, claim 60 has been made dependent on claim 58, and the word "stent" in line 1 has been deleted, and in claim 75, the word "it" has been replaced by "thereon".

Claims Rejections under 35 USC 102 and 35 U.S.C. 103

Claims 1-3, 5-6, 17-18, 21-25, 27-29, 58, 60, 64, and 75-77:

These claims stand rejected under 35 USC 102(a) or (e) as being anticipated by Shanley U.S. Patent 6,293,967 (Shanley). Applicant respectfully traverses this rejection.

Claim 1 has been amended to incorporate the features of claim 11, and now reads:

A deformable medical implant, comprising:

a body defining at least two implant points, which body is adapted to be deformed so that the at least two implant points are moved relative to each other;

at least two elongate extensions, each extension fixed to one implant point;

a bridge coupling at least two of said extensions to each other; and

at least two hinges defined on said at least one of said at least two elongate extensions, two of said at least two hinges having different preferred bending directions and being defined on one of said at least two elongate extensions,

wherein said hinges operate to bend said extensions in a direction including a component perpendicular to a device plane of said body, when said implant points are moved apart, said device plane being a substantially two-dimensional mathematical surface conforming to the general geometry of the device.

Nowhere in Shanley is there a disclosure, teaching, or suggestion of a structure in which hinges operate with extensions to bend the extensions in a direction including a component perpendicular to a device plane of body (as defined in the claim). The bending of Shanley's hinges only provide improved uniformity of expansion, and concentration of expansion forces in small, well defined areas while limiting strut deflection and plastic strain to specified levels (see, for example Col. 4, lines 23-36).

Claims 1-6, 12-19, 21-30, 34-38, 28-60, 64, 66-69, 71-72, and 74-77:

The Examiner's rejection of the previous version of claim 1 and of now canceled claim 11 under 35 U.S.C. 103 as being unpatentable over Vardi U.S. patent 6,325,826 (Vardi) in view of Shanley and Vargas et al. U.S. Patent No. 6,428,550 (Vargas) is noted. Applicant respectfully disagrees with the Examiner's reasoning supporting this rejection. Because the essential features of claim 11 now appear in claim 1, that rejection will now be addressed. The rejection of claims 2-6, 12-19, 21-30, 34-38, 28-60, 64, 66-69, 71-72, and 74-77 over the combination of Vardi, Shanley and Vargas will also be addressed.

Applicant respectfully submits that Vardi is an example of what a person having ordinary skill in the art might do when confronted with applicant's problem, but who lacked the inventive insight to have created a device as described in the present claims. Referring to Fig. 10 of Vardi, as cited by the Examiner, this simply shows a hole 102 through which a separate side stent enters the bifurcation after the main stent has been inserted and anchored. This process, involving separate insertion and expansion steps for each of the two separate stents is in contrast to the unitary construction and single expansion step of claim 1.

To incorporate the hinge structure of Shanley in Vardi, as proposed by the Examiner, won't overcome the fatal deficiency in Vardi since Shanley does not have a part that expands out of the device plane of the body. Moreover, the Examiner has not demonstrated any teaching of how a person having ordinary skill in the art would modify Vardi, especially since Vardi is not a unitary device, and has nothing to be expanded out of the device plane.

Not only does Vargas not solve the problem in the combination of Vardi and Shanley, but the Examiner's application of it is a classic case of hindsight reconstruction based on applicant's own teachings.

Vargas relates to an anastomosis device sized and shaped for connecting a graft vessel to a target vessel, (see column 4, lines 10-25, column 6 lines 9-21, and FIGS. 4 and 5), by placing the graft in an opening formed in the target vessel (see column 4 lines 38-52). Such an opening cannot be formed using a stent. Nor would a stent serve any purpose in this application. In short, Vargas does not disclose, teach, or suggest a stent, nor does it bear any physical or functional resemblance to a stent. It no more involves the same field of technology as a stent, than do a bicycle and a motorcycle or a baseball and a basketball.

Moreover, the flaring part of the Vargas device is merely an anchoring device which provides for sutureless attachment. There is nothing in Vargas, Vardi or Shanley from which a person having ordinary skill in the art could recognize that part of a stent can be flared to support the bifurcation point, or how to do so, even given the inspiration. Only applicant recognized this possibility and the means to bring it about. Claim 1 is thus not rendered obvious by the Examiner's proposed combination of Vardi, Shanley and Vargas.

Since amended claim 1 is neither anticipated by Shanley, nor unpatentable over the combination of Vardi, Shanley and Vargas, dependent claims 2-3, 5-6, 17-18, 21-25, 27-29, 58, 60, 64, and 75-77 are consequently allowable over Shanley. Claims 2-6, 12-19, 21-30, 34-38, 28-60, 64, and 75-77 are allowable over the combination of Vardi, Shanley and Vargas for the same reasons.

Claim 74 is directed to a stent comprising:

an expandable cylindrical body sized and shaped to be implanted in a vascular bifurcation between a blood vessel and a side branch thereof;

an aperture defined in a side of said expandable cylindrical body and designed for allowing passage to said side branch;

at least two extensions mounted adjacent said aperture; and

at least two hinges defined on at least one of said extensions so as to allow extending said at least two extensions away from said body, as an outcome of an expansion of said expandable cylindrical body.

The foregoing arguments concerning the combination of Vardi, Shanley and Vargas apply with equal force to the rejection of independent claim 74. Nothing in these references can be combined to produce a structure in which "at least two hinges defined on at least one of said extensions so as to allow extending said at least two extensions away from said body, as an outcome of an expansion of said expandable cylindrical body" without resort to applicant's own teachings.

This claim is allowable over the combination of Vardi, Shanley and Vargas for the same reasons.

These arguments concerning the combination of Vardi, Shanley and Vargas also apply to the rejection of independent claim 66 and its dependent claims 67-69 and 71, 72.

Claim 66 is directed to a stent comprising:

(a) an expandable cylindrical body;

(b) an aperture defined in a side of the body and designed for allowing passage to a side branch;

(c) at least two extensions mounted adjacent said aperture and configured to be extended away from said body by an expansion of said body.

Nothing in Vardi, Shanley, or Vargas can be combined to create a structure meeting the terms of (c) above without resort to applicant's own teachings for the same reasons as discussed above in connection with claim 1. Claim 66 and its dependent claims are therefore also allowable.

Claims 4 and 26

These claims stand rejected under 35 U.S.C. 103 as being unpatentable over Shanley. This rejection is traversed for all the same reasons stated above in connection with claim 1, upon which these claims depend. There is no disclosure, teaching, or suggestion in Shanley of hinges which operate with extensions to bend the extensions in a direction including a component perpendicular to a device plane of body.

Claim 19

This claim stands rejected under 35 U.S.C. 103 as being unpatentable over Shanley in view of Vargas. As in the case of claims 4 and 26, this rejection is traversed for all the same reasons stated above in connection with claim 1, upon which these claims depend. There is no disclosure, teaching, or suggestion in Shanley of hinges which operate with extensions to bend the extensions in a direction including a component perpendicular to a device plane of body. The Examiner's reliance on Vargas to show the equivalence of different hinge constructions does nothing to overcome the fatal deficiency in Shanley.

Claim 70

This claim stands rejected under 35 U.S.C. 103 as being unpatentable over the combination of Vardi, Shanley and Vargas, and further in view of Globerman U.S. patent 6,402,777 (Globerman). This rejection is traversed for all the same reasons stated above in connection with the rejection based on the combination of Vardi, Shanley and Vargas alone. The Examiner has relied on Globerman only for its teaching of a radiopaque marker. Globerman does nothing to overcome the fatal deficiencies in the combination of Vardi, Shanley and Vargas discussed above.

Claims 39-43, 61-63, and 73:

These claims stand rejected under 35 USC 103 as being unpatentable over Vardi in view of Vargas.

Claim 39 and its dependent claims 40-43 and 61, are directed to a method of distorting a stent structure having at least two extensions coupled at a point thereof and sized and shaped to be placed in a vascular bifurcation. The method, as described in claim 39, comprises:

changing the relative position of two points on said extensions that are distanced from said coupling point;

transforming, using a plurality of pre-defined hinges, tension forces applied by said changing into forces that bend said structure in a plane outside of a plane defined by said changing.

As previously explained, except by resort to applicant's own teachings, nothing in Vardi or Vargas can legitimately be combined to create a structure in which "tension forces applied by [changing the relative position of two points on extensions on the stent] are changed "into forces that bend said structure in a plane outside of a plane defined by said changing."

Claim 39 and its dependent claims are therefore also allowable.

Claim 73 is directed to a method for deploying a stent, comprising:

guiding an expandable cylindrical body to a vessel bifurcation between a main vessel and a side vessel;

expanding said expandable cylindrical body in said vessel bifurcation;
and

extending away at least two extensions of said expandable cylindrical body from said body, into said side vessel, said extending being brought about by said expanding.

As discussed above in connection with claim 39, except by resort to applicant's own teachings, nothing in Vardi or Vargas can legitimately be combined to create a structure in which "at least two extensions of said expandable cylindrical body [are extended away] from said body, into said side vessel, said extending being brought about by said expanding".

Claim 73 is therefore also patentable.

New claim 78 reads as follows:

A stent for a bifurcation of a blood vessel comprising:

an expandable body having first and second parts joined to form a unitary structure,
the body having a longitudinal axis and a surrounding surface, and
defining a plurality of points of implantation for engaging the interior of the blood vessel,

wherein the body is deformable to move the implant points relative to each other;

the body including a plurality of elongated extensions, fixed to the implant points; and

two hinges formed on at least one of said extensions, said two hinges having different preferred bending directions,

wherein, upon application of an expansion force to said body, the first part of the body enlarges outwardly, and one or more of the extensions comprised in the second part move away from the surface of the body and become oriented at an angle to the longitudinal axis of the body corresponding to the angle of the bifurcation.

There is nothing in Shanley, or in any combination of Shanley, Vardi and Vargas which does not depend on applicant's own teachings by which a structure can be created in which ". . . upon application of an expansion force to said body. . . one or more of the extensions comprised in the second part move away from the surface of the body and become oriented at an angle to the longitudinal axis of the body corresponding to the angle of the bifurcation.'

Claim 79 reads as follows:

A deformable medical implant, comprising:

an expandable body having a longitudinal axis and a surrounding surface, said body defining a plurality of implant points, wherein the body is deformable to move the implant points relative to each other;

a plurality of elongated extensions, each extension respectively fixed to one implant point;

a bridge coupling two of said extensions to each other; and

two hinges formed on at least one of said extensions, said two hinges having different preferred bending directions,

wherein, upon expansion of said body, at least one of said extensions moves out of the surface of the body and is oriented at an angle to the longitudinal axis of the body.

As in the case of claim 78, there is nothing in Shanley, or in any combination of Shanley, Vardi and Vargas which does not depend on applicant's own teachings by which a structure can be created in which ". . . upon expansion of said body, at least one of said extensions moves out of the surface of the body and is oriented at an angle to the longitudinal axis of the body". Claims 78 and 79 should consequently also be allowed.

All of the issues raised by the Examiner having been addressed, and the added claims have been demonstrated to be allowable. It is therefore respectfully submitted that the application is in condition for allowance. Early notice thereof is accordingly respectfully solicited.

Respectfully submitted,

/Jason H. Rosenblum/

Jason H. Rosenblum
Registration No. 56,437
Telephone: 718.246.8482

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Enclosures:

- Formal Drawing Transmittal Sheet
- Complete Set of Replacement Drawing Sheets (including New Figure 8G on Drawing Sheet "6/12")